

with the use of a single approach (such as a single centre), (iii) the health state of the participant, and (iv) the burden on site staff affecting recruitment. The protocol addresses issue (i) by describing effectiveness in terms of time to need for new treatment rather than disease progression as well as cognitive debriefing; issues ii & iv using a broad spectrum of recruitment methods; (iii) minimising patient burden. **CONCLUSIONS:** The development of this protocol has been informed by lessons learnt from previous research. An analysis of the issues identified as limitations in previous studies in collecting patient preference data allows improvements in protocol design.

PCN240

PATIENTS' PREFERENCES REGARDING THE SETTING OF ELECTRONIC PATIENT-REPORTED OUTCOME ASSESSMENTS

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OBJECTIVES: Patient-reported outcomes (PRO) provide a more comprehensive picture of patients' quality of life than do mere physicians' ratings. Electronic data collection of PRO offers several advantages and allows assessments at patients' homes as well. This study reports on patients' internet use, their attitudes towards electronic and web-based PRO assessment (clinic-ePRO and home-ePRO) and the feasibility of these two assessment modes. **METHODS:** At the Medical University of Innsbruck and Kufstein County Hospital, cancer patients who participated in clinic-ePRO/home-ePRO were asked to complete a comprehensive evaluation form on their internet usage, attitudes towards and the feasibility of routine clinic-ePRO/home-ePRO with the Computer-based Health Evaluation System (CHES) software. **RESULTS:** In total, 158 patients completed the evaluation form. Most patients expressed willingness to complete routine clinic-ePRO (92.3%)/home-ePRO (70%) assessments in the future and to discuss such data with attending physicians (82.2%). The CHES software for home-ePRO was preferred over phone interviews by 95.7% of patients and 72.7% experienced it as easy to use. Only a few minor suggestions for improvement were made. Overall satisfaction with home-ePRO was high with an average rating of 9.1 points (range 5–10 points). However, there became an age bias apparent, as participating patients were approximately ten years younger than those refusing clinic-ePRO/home-ePRO. **CONCLUSIONS:** The use of clinic-ePRO/home-ePRO was in general shown to be feasible and well accepted. However, to be more inclusive in the implementation of clinic-ePRO/home-ePRO, educational programs concerning their particular benefit in oncology practice potentially could enhance patients' attitudes towards, and consequently their acceptance of and compliance with electronic PRO assessments.

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EFFECTS OF ADVERSE EVENTS ON QUALITY OF LIFE SCORES IN A RANDOMIZED CLINICAL TRIAL OF ADJUVANT CHEMOTHERAPY FOR BREAST CANCER: N-SAS BC 02

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OBJECTIVES: To investigate the effects of adverse events on quality of life (QOL) scores during adjuvant chemotherapy for breast cancer patients. **METHODS:** We analyzed the QOL scores assessed by EQ-5D and the worst grades of adverse events assessed by the National Cancer Institute - Common Toxicity Criteria (NCI-CTC) Version 2.0 collected from a national multicenter phase III randomized clinical trial: National Surgical Adjuvant Study of Breast Cancer-02 (N-SAS BC 02), which compared two types of taxane-containing chemotherapy, as an approved sub analysis numbered CSP-HOR22. A linear regression model was constructed with change in EQ-5D score as an objective variable, calculated as the worst scores minus the baseline (before chemotherapy) scores, and the incidences of adverse events as independent variables, set as binary variables regardless of grade. **RESULTS:** From 300 participants, 250 complete series of data of EQ-5D scores and adverse events were extracted. The average baseline EQ-5D score was 0.798. The average of worst EQ-5D scores for each participant during chemotherapy was 0.720 and the average change in EQ-5D score was -0.078, with a range of -0.619 to +0.464. Although QOL deteriorated in 140 patients, it improved in 54 patients. Seventeen adverse events were selected as independent variables excluding rare ones. The following three coefficients of the regression model were significant; edema: -0.056 (p=0.03), phlebitis: 0.068 (p=0.01), and sensory nerve disturbance: -0.084 (p<0.01), and these results are equivalent to simple linear regression models for each factor. **CONCLUSIONS:** Cases of QOL improvement events may have reduced the model's descriptive power and caused a positive coefficient value. Since patients treated with taxane-containing chemotherapy often suffer sensory nerve disturbance as well as edema for a longer period, even after the termination of chemotherapy, clinicians should provide selective care to avoid deterioration of patients' QOL.

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MEASUREMENT OF HOPE IN PATIENTS WITH CANCER

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OBJECTIVES: To understand the ways in which hope and related constructs are applied and measured in the context of healthcare, especially in patients with cancer. Targeted literature reviews were conducted in two areas: (1) Psychological assessments measuring hope, and (2) Measures of psychological function in cancer-related care, including well-being and other positive psychological constructs. **METHODS:** To better understand the scope of psychological assessments developed and currently in use to measure hope and related positive psychological constructs in the context of healthcare, a targeted review of the published literature was undertaken. MEDLINE and PsychINFO database searches were conducted for publications in English in the past 5 years. **RESULTS:** 876 abstracts on the meas-

urement of hope and 639 abstracts on the measurement of psychological function in cancer were screened to identify publications focusing on the development of psychological instruments. In some cases, an article describing a promising instrument was selected and then used to identify the original validation study which was then substituted as the article selected for full text review. 16 measures with a hope focus or hope-specific items were identified for further review and 9 measures of positive psychological constructs developed for use in the context of cancer were identified for further review. **CONCLUSIONS:** Positive psychological constructs factor into cancer treatment and symptom remission. Measurement of these domains is an important component of treatment selection and outcomes assessment. However, reliable and valid assessment of hope and related constructs depends on the availability of psychometrically sound instruments developed for this context of use. The present study demonstrates that while much work has been done in research settings to develop such measures, there is still a need for further refinement and development of these tools so that they are fit for use in a regulated research context.

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DEVELOPMENT OF A WEB-BASED QUALITY OF LIFE PORTAL FOR BREAST CANCER PATIENTS

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OBJECTIVES: Overall aim of this study is to evaluate acceptability and usability of the Quality of Life-Portal (QOL-Portal), developed for breast cancer patients. The portal is designed for assessing information needs and patient's QOL and enhancing patient education as well as health literacy. **METHODS:** Software development has been done in close collaboration with a multidisciplinary group of healthcare professionals following an Extreme Programming approach. This means that software development was based on an stepwise process that included the evaluation of individual components of the portal by healthcare professionals and subsequent adaptation in accordance with the provided feedback. Currently, we are conducting semi-structured interviews in breast cancer patients to collect information on acceptability and usability of the QOL-Portal. The main evaluation criteria are divided into usability (e.g. possible problems with web-access, user-friendliness and satisfaction) and content (e.g. understandability of information and of graphical questionnaire presentation). **RESULTS:** Software development has been completed and resulted in an online QOL portal for breast cancer patients. Based on feedback from healthcare professionals we developed several components for the portal: an information module to enhance patients' condition and treatment related knowledge, health literacy, a symptom monitoring tool based on the EORTC questionnaires (allowing assessments in the hospital and at home), and a basic set of self-help interventions. In addition, the portal provides graphical feedback on the QOL results to patients themselves. Preliminary results from the ongoing patient interviews will be presented at the conference. **CONCLUSIONS:** QOL-Portals are gaining importance as they allow routine symptom assessment and provide important information to patients and medical alike. We have developed key components for the portal which undergo further adaption and improvement based on feedback from healthcare professionals and patients. In a next step, we will evaluate the impact of the portal on patients' QOL.

PCN244

HEALTH RELATED QUALITY OF LIFE OF CAREGIVERS AND PATIENTS TREATED FOR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH ORAL VINORELBINE

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OBJECTIVES: Oral chemotherapy was developed to reduce in-patient stays while providing the same level of efficacy and safety. This study assessed the health-related quality of life (HRQoL) of patients treated with oral vinorelbine for metastatic NSCLC and their caregivers. **METHODS:** This longitudinal survey assesses 2 visits documenting the second and third chemotherapy cycles. Patients had metastatic NSCLC and received oral vinorelbine (day 1 and 8 of 3-week cycles) and carboplatin (day 1). Baseline measures included demographics, anamnesis, co-morbidities and current treatment. SF-12 was reported at the end of each cycle, on the patients and interestingly on the caregivers. **RESULTS:** Three Danish centers included 45 patients: median age: 66.9 y.o., 53.3% were male. Performance status (ECOG) was 0: 33.3%; 1: 51.1%; 2+: 15.6%. Main reason for choosing oral vinorelbine was convenience. Caregivers, mainly spouses (76.7%), were 57.8 y.o. No major change on SF-12 scores was reported between cycle 2 and 3. Physical summary scores (PCS) of patients (37.0-38.6, respectively cycle 2 and 3) were lower than those of caregivers (52.9-53.4) and general population (44). Mental summary scores (MCS) of patients (47.7-44.2) and caregivers (46.2-44.6) were much lower than those of a population of same age (patient: 52; caregiver: 51). The most affected patient scores were physical functioning (40.4), role physical (40.1), vitality (37.2). Social functioning (SF) was similarly high in patients and caregivers (76.9 vs. 78.9, patient vs. caregiver) while mental health of both patients and caregivers were lower (66.7 vs. 65.5) than SF. **CONCLUSIONS:** Metastatic NSCLC deeply affects patients' HRQoL as measured by a generic instrument, both on MCS and PCS. Caregivers' HRQoL is also affected, mainly on MCS. Patients receiving oral vinorelbine plus carboplatin and their caregivers maintain a good level of social functioning.

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BURDEN OF ADVANCED BREAST CANCER FOR PATIENTS AND CAREGIVER IN EUROPE: COMPARISONS OF TWO TREATMENT FORMS OF VINORELBINE, ORAL AND INTRAVENOUS

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